AGENDA

GASTROENTEROLOGY AND UROLOGY DEVICES PANEL
OF THE
MEDICAL DEVICES ADVISORY COMMITTEE
January 17, 2003

Panel Chair: Karen L. Woods, M.D
Clinical Associate Professor of Medicine
Baylor College of Medicine
Houston, Texas

Location: Hilton Washington, D.C. North (formerly known as Gaithersburg Hilton)
Gaithersburg, Maryland

***NOTE:* Two ten minute breaks and a one-hour lunch break will be determined at the discretion of the panel chair.**

CALL TO ORDER: **8:30 a.m.**

OPEN PUBLIC HEARING **8:45 a.m. (30minutes)**

Public attendees will be given an opportunity to address the Panel to present data or their views on the Panel's activities.

OPEN COMMITTEE DISCUSSION

1. Sponsor Presentation: **To follow (75 Minutes)**

1. Company, Device Description & Pre-Clinical Studies – Alan Stein, PhD, President and Chairman, Enteric Medical Technologies
2. Histopathology Review: Pre-Clinical Studies – Lucas Brennecke, DVM, DACVP, Director, Medical Device Pathology, Pathology Associates, a Division of Charles River Laboratories, Inc.
3. Study Design and Results: Safety – Glen Lehman, M.D., Professor of Medicine and Radiology, Indiana University
4. Study Results: Effectiveness – David Johnson, M.D.,Professor of Medicine, Eastern Virginia Medical School
5. Study Conclusions – Alan Stein, PhD, President and Chairman, Enteric Medical Technologies

2. FDA Presentation: **To follow (75 Minutes)**

1. Overview/Pre-Clinical Studies – Kathleen Olvey, FDA/ODE/DRARD/GRDB Scientific Reviewer
2. Histopathology Considerations – Katharine Merritt, Ph.D., FDA/OST/DLS/HSB
3. Clinical Considerations – Aron Yustein, M.D., FDA/ODE/DRARD/GRDB Medical Officer
4. Statistical Considerations – Melvin Seidman, FDA/OSB/
5. Post Market Review – S. Lori Brown, Ph.D. FDA/OSB/

Proposed Lunch - 1 hour **12:00 p.m.**

3. Panel Discussion: **1:00 p.m.**

The committee will discuss FDA charges, make recommendations and vote on a premarket approval application P020006 from Enteric Medical Technologies and Boston Scientific for a device for the treatment of gastroesophageal reflux disease.

1. Dr. Brian Fennerty – Primary Review and Lead Discussant.
2. Reading of Questions and Discussion.

OPEN PUBLIC HEARING **To follow**

Public attendees will be given an opportunity to address issues specific to the matter before the committee.

4. Final Comments

1. FDA Comments
2. Sponsor Comments

5. Panel Deliberations and Vote

6. Adjournment